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EXAMINER

MAHATAN, CHANNING

ART UNIT PAPER NUMBER

1631

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|------------------------------------|--|
| Office Action Summary | Application No. 09/807,943 | Applicant(s) HONG ET AL. | |
| | Examiner Channing S. Mahatan | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☒ Claim(s) 2-5 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input checked="" type="checkbox"/> Other: <i>Attachment for PTO-948</i> . |

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DETAILED ACTION

ART UNIT DESIGNATION

The Group and/or Art Unit designated for this application has changed. Applicants are hereby informed that future correspondence regarding this application should be directed to Group Art Unit 1631.

OBJECTION BY DRAFTSMAN

Applicants are hereby notified that the required timing for correction of drawings has changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Due to the above notification applicants are required to submit drawing corrections with the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-17.

Claims Rejected Under 35 U.S.C § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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VAGUE AND INDEFINITE

Claims 8 (lines 7-11) and 15 (lines 7-11) are vague and indefinite in that “said potential energy value being proportional to the spacing between adjacent peaks of the cluster and to the amount of displacement required to bin the peaks into discrete size bins” but confusingly without indicating what the algorithm is which determines the “proportionality”. Proportional implies some kind of relationship that is properly related in size or other measurable characteristics. Since the specification is believed to specify the “proportionality” algorithm, the claim is not commensurate in scope with the specification because of the unspecific claim versus the non-commensurate specification.

Claims 9 (lines 8-9), 16 (lines 9-10), 17 (lines 11-12), and all claims dependent therefrom recite the phrases “starting size of said fragments” and “ending size of said fragments” which is vague and indefinite. It is unclear how the size of said fragments would change between “starting” and “ending”. If the size of said fragments do change, it is then unclear at what point applicants regard as “starting” and “ending”. Clarification is required via clearer claim wording.

Claim 11 (lines 3-5) recites the phrase “a score obtained by matching one of said two data records to itself” which is vague and indefinite. It is unclear what the “matching” criteria/algorithm is to which the score is obtained. Is it applicants’ intent that this score (rather than “said score”) is obtained through the steps of instant claim 10? Clarification is required, via clearer claim wording.

LACK OF ANTECEDENT BASIS

Claims 1 (lines 11-12), 12 (lines 13-14), and all claims dependent therefrom recites the limitation “a sequence determined by said aligned sizes” which lacks proper antecedent basis.

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The aligning step states “aligning the sizes of said fragments into corresponding ones of discrete size bins”, there is no indication in claims 1 or 12 that “a sequence is determined by said aligned sizes”. Thus, there is insufficient antecedent basis for this limitation in the claim.

Claims Rejected Under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, and 5-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ghosh et al. taken in view of McEnvoy et al.

Ghosh et al. describes a method of sizing with automated binning of data from different sequencing machines to minimize allele size variation (Abstract). The authors define binning or allele calling to be the unique categorization of each allele of a marker by the assignment of an integer label (mean size), wherein each bin can be described by the bin label, mean, range, and standard deviation (instant claim 1) (page 166, Column 2, lines 3-8). Ghosh et al. normalizes data to mean sizes and adjusts each marker's allele sizes independently of other markers through an external adjustment algorithm by comparing the sizes of marker alleles from a standard with the genotype run on each gel (instant claims 6, 7, 13, and 14)(page 169, Column 1, lines 12-38). It is stated that GENOTYPER™ can be utilized to find means and standard deviations for all allele categories and then assign them a bin label, however, such methodology would be time-consuming, tedious, memory intensive, and error prone (page 169, Columns 1-2, lines 43-48 and 1-2, respectively). Therefore, the development of a binning algorithm that sorts each marker

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allele from the total data according to size was required. The binning algorithm set forth creates a new bin when the size difference between two sequentially sized alleles is greater than the set tolerance level (represents the minimum allowable distance between adjacent bins in base pairs) until all alleles are binned, and a bin label (equal to the mean sizes rounded up to the nearest whole numbers) is assigned to each group/cluster (page 169, Column 2, lines 13-33).

Additionally, for alleles one (1) base apart the tolerance level for alleles 1 base apart is set at 0.2 bp to minimize binning error. Further, the authors have written software to carry out the binning and adjustment algorithm automatically (instant claims 12-16) (page 169, Column 2, lines 33-36). Ghosh et al. describes and illustrates the data flow from raw genotype to statistical genetic analysis files and said files are stored for future reference (instant claims 9 and 17) (page 172, Column 1-2 and Figure 4). However, Ghosh et al. fails to state that the initial raw data prior to sizing and binning of alleles is derived from measured peak intensities and assigning an arbitrary value (i.e. potential energy as in instant claims 8 and 15) to each cluster representative of the space between adjacent peaks.

McEnvoy et al. examines the utilization of the PE Applied Biosystems Model 373 Automated DNA Sequencer™ and GENESCAN™ software (Versions 1.2.1, 2.0.2 or 2.1 (page 468, Column 2, lines 1-3)) to size minisatellite alleles (Abstract) from samples obtained by restriction fragment length polymorphism and variable number tandem repeat (instant claims 1, 2, and 5) (page 464, Column 3, lines 14-16; Tables 1 and 2). The authors illustrate measured peak intensities and respective nucleotide distances from a sample, using a DNA sequencer data, on an electropherogram (Figures 1 and 2); particularly Figure 1A illustrates the normalization of 6 samples. To determine the size calling variability within- and between-gel McEnvoy et al.

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analyzed series of gels and present the size calling precision with standard deviation of .4-2.5 bp observed (Table 1) demonstrating discrete levels for each allele (minisatellite alleles 2-12).

However, McEnvoy et al. fails to categorize each allele in the sample by allele calling or binning.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the invention to practice Ghosh et al., method of sizing with automated binning of sequencing machine data with McEnvoy et al. sizing minisatellite alleles from raw data obtained through measuring peak intensity and binning by respective nucleotide distances (instant claim 8, 10, and 11) since both Ghosh et al. and McEnvoy et al. analyze sequencing machine data from a PE Applied Biosystems Model 373 Automated DNA Sequencer TM and GENESCAN TM software and utilize GENESCAN TM software to size alleles.

Claims 1-17 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Ghosh et al. taken in view of McEnvoy et al. further in view of Young et al.

Ghosh et al. taken in view of McEnvoy et al. describes a method of sizing with automated binning of measured peak intensity from a sample obtained by restriction fragment length polymorphism or variable number tandem repeat technique (Refer to above 103 (a) Rejection). However, Ghosh et al. taken in view of McEnvoy et al. fails to indicate that the sample analyzed is obtained by amplified fragment length polymorphism or simple sequence repeats.

Young et al. provides a genetic linkage map of rainbow trout through the analysis of the chromosomal distribution of minisatellite markers (Abstract). The analysis of the chromosomal distribution was performed through a variety of techniques; i.e. amplified fragment length polymorphism, simple sequence repeats, variable number tandem repeat, etc. (pages 840-841).

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Thus, it would have been obvious to someone of ordinary skill in the art at the time of the invention to practice Ghosh et al. taken in view of McEnvoy et al., method of sizing and automated binning of alleles from data obtained by restriction fragment length polymorphism and variable number tandem repeat with Young et al. data obtained by amplified fragment length polymorphism or simple sequence repeats (instant claims 3 and 4) since Young et al. states that these techniques detect high levels of variability which would allow for the rapid analysis of large numbers of informative loci (page 840, Column 1, lines 38-41). Further, the method described by Ghosh et al. reduces allele size variation, combines data from different sequencing machines, and is automated (Abstract).

OBJECTION OF CLAIMS

Claims 2-5 are objected to because of abbreviations (i.e. ALFP), which are improper.

Appropriate Correction Is Required.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.


Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

September 6, 2002

Examiner Initials:

CSM


MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600